



Bruxelles, 28.11.2014
C(2014)9277 (final)

COMMISSION IMPLEMENTING DECISION

of 28.11.2014

**amending the marketing authorisation granted by Decision C(2013)4019(final) for
“Xtandi - enzalutamide”, a medicinal product for human use**

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹,

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products², and in particular Article 17(2) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Astellas Pharma Europe B.V. in accordance with Regulation (EC) No 1234/2008,

Having regard to the opinions of the European Medicines Agency, formulated on 25 September 2014 and on 23 October 2014 by the Committee for Medicinal Products for Human Use,

Whereas:

- (1) The European Medicines Agency's opinion is favourable to the variation of the terms of the decision granting the marketing authorisation as submitted by the marketing authorisation holder.
- (2) The review of the data submitted by Astellas Pharma Europe B.V. on 25 April 2014 has shown that the new therapeutic indication proposed for the medicinal product "Xtandi - enzalutamide" brings significant clinical benefit in comparison with existing therapies. Therefore, an additional year of marketing protection in accordance with Article 14(11) of Regulation (EC) No 726/2004 should be granted.
- (3) Decision C(2013)4019(final) should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 334, 12.12.2008, p. 7.

- (4) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2013)4019(final) should therefore be replaced.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2013)4019(final) is amended as follows:

- 1) Annex I is replaced by the text set out in Annex I to this Decision;
- 2) Annex II is replaced by the text set out in Annex II to this Decision;
- 3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

Based on the conclusions set out in annex IV to this Decision, the additional year of marketing protection is granted in accordance with Article 14(11) of Regulation (EC) No 726/2004.

Article 3

This Decision is addressed to Astellas Pharma Europe B.V., Sylviusweg 62, NL-2333 BE Leiden, Nederland.

Done at Brussels, 28.11.2014

For the Commission

Ladislav MIKO

Acting Director-General